CLAIMS

What is claimed is:

1. A pharmaceutical composition for oral administration comprising a granulation, said granulation comprising CCI-779, a water soluble polymer, a surfactant, an antioxidant, and a pH modifying agent.

2. The composition of claim 1, wherein the water soluble polymer is PVP, hydroxypropylmethylcellulose, polyethylene glycol, or cyclodextrin or mixtures thereof.

3. The composition of claim 2, wherein the water soluble polymer is PVP.

4. The composition of claim 3, wherein the surfactant is polysorbate 80, sodium lauryl sulfate, sodium dodecyl sulfate, a salt of a bile acid, an ethoxylated vegetable oil, a polyoxyethylene-polyoxypropylene block copolymer, or a poloxamer.

5. The composition of claim 4, wherein the surfactant is sodium lauryl sulfate or sodium dodecyl sulfate.

6. The pharmaceutical composition of claim 5, wherein the pH modifying agent is sodium citrate, citric acid, or dilute hydrochloric acid.

7. A process for preparing a CCI-779 oral composition, which comprises

(a) dissolving CCI-779 and an antioxidant in an alcohol to form an alcoholic solution;

(b) dissolving PVP, a pH modifying agent, and a surfactant in water to form an aqueous solution;

(c) mixing the alcoholic solution and the aqueous solution to form a hydroholic solution.

(d) adding the hydroholic solution to a mixer containing one or more intragranular excipients;

(e) granulating the mixture; and

(f) drying the resulting granulation.

8. A process for preparing a CCI-779 oral composition, which comprises
   (a) dissolving CCI-779 and an antioxidant in an alcohol to form an alcoholic solution;
   (b) dissolving PVP, a pH modifying agent, and a surfactant in water to form an aqueous solution;
   (c) adding the aqueous and alcoholic solutions stepwise, and in one or more portions each, to a mixer containing one or more intragranular excipients;
   (e) granulating the mixture; and
   (f) drying the resulting granulation.

9. A CCI-779 oral composition prepared by wet granulation.

10. A CCI-779 oral composition prepared the process comprising
   (a) dissolving CCI-779 and an antioxidant in an alcohol;
   (b) dissolving PVP, a pH modifying agent, and a surfactant in water;
   (c) combining the aqueous and alcoholic solutions to provide a hydroholic solution;
   (d) adding the hydroalcoholic solution to a mixer containing one or more intragranular excipients;
   (e) granulating the mixture; and
   (f) drying the resulting granulation.

11. The composition of claim 10, wherein the pH modifying agent is selected from the group consisting of citric acid, sodium citrate, hydrochloric acid and mixtures thereof.

12. The composition of claim 11, wherein the alcohol is ethanol.

13. The composition of claim 12, wherein the antioxidant is butylated hydroxyanisole and butylated hydroxytoluene.

14. The composition of claim 13, wherein the surfactant is sodium lauryl sulfate.

15. A CCI-779 oral formulation prepared by the process comprising

(a) dissolving CCI-779 and an antioxidant in an alcohol;

(b) dissolving PVP, a pH modifying agent, and a surfactant in water;

(c) adding the aqueous and alcoholic solutions stepwise, and in one or more portions each, to a mixer containing one or more intragranular excipients;

(e) granulating the mixture; and

(f) drying the resulting granulation.

16. The composition of claim 15, wherein the pH modifying agent is selected from the group consisting of citric acid, sodium citrate, hydrochloric acid and mixtures thereof.

17. The composition of claim 16, wherein the alcohol is ethanol.

18. The composition of claim 17, wherein the antioxidant is butylated hydroxyanisole and butylated hydroxytoluene.

19. The composition of claim 18, wherein the surfactant is sodium lauryl sulfate.